

Notice of Allowability

Application No.

09/095,639

Examiner

Thái-An N. Ton

Applicant(s)

POZZILLI, PAOLO

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/14/03.
2. ☒ The allowed claim(s) is/are 28-51.
3. ☒ The drawings filed on 11 June 1998 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>6</u> | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

Deborah Crouch

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with James Costigan on October 31, 2003.

The application has been amended as follows:

In the claims:

1. Replace claim 28 with the following:
 28. A dietary or pharmaceutical product, said product comprising at least one bovine beta-casein selected from the group consisting of recombinant or synthetic beta-caseins which do not contain the sequences: Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2).
2. Replace claim 29 with the following:
 29. The product according to claim 28 wherein in the sequences Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2), the sequences are modified by the steps of:
 - a) removal of said sequences;
 - b) substitution of said sequences by the sequence Val-Glu-Pro-Ile-Pro (SEQ ID NO: 6); or
 - c) a combination of steps a) or b).

3. In claim 30, line 2 insert the term – beta- – before the term caseins.
4. In claim 31, line 2 insert the term – beta- – after the term bovine.
5. In claim 31, line 3 delete the phrase, “or fragments thereof”.
6. In claim 31, line 5 insert the term – beta- – after the term vegetable.
7. In claim 32, line 2 insert the term – beta- – before the term casein.
8. In claim 32, line 4 insert the term – beta- – before the term casein.
9. In claim 32, line 7 insert the term – beta- – before the term casein.
10. Replace claim 33 with the following:
 33. A method for the inhibition of the inductive effect of beta casein on insulin-dependent diabetes comprising the step of administering to newborns and infants an infant formula free of beta caseins that exhibit molecular mimicry with protein GLUT2.
11. In claim 34, line 3 insert the term – beta- – before the term caseins.
12. Replace claim 35 with the following:
 35. A method for the inhibition of the inductive effect of beta casein on insulin-dependent diabetes in infants and newborns comprising the step of administering an infant formula comprising at least one beta-casein selected from the group consisting of naturally occurring, recombinant, synthetic animal or vegetable beta-caseins not containing the sequences: Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2).
13. In claim 36, delete the phrase, “and its fragments” in line 2.
14. In claim 36, line 5, insert the term – beta- – before caseins.
15. In claim 36, line 6, insert the term – beta- – before casein.
16. In claim 36, line 8, insert the term – beta- – before casein.

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17. In claim 36, line 12, insert the term – beta- – before casein.
18. Replace claim 37 with the following:
 37. A product comprising at least one bovine beta-casein selected from the group consisting of recombinant or synthetic beta-caseins which do not contain the sequences: Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2).
19. Replace claim 38 with the following:
 38. The product according to claim 37 wherein in the sequences Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2), the sequences are modified by the steps of:
 - a) removal of said sequences;
 - b) substitution of said sequences by the sequence Val-Glu-Pro-Ile-Pro (SEQ ID NO: 6); or
 - c) a combination of steps a) or b).
20. In claim 39, line 1 insert the term – beta- – before the term caseins.
21. In claim 40, line 2 delete the phrase, “or fragments thereof”.
22. In claim 40, line 4 insert the term – beta- – before the term caseins.
23. In claim 41, line 2 insert the term – beta- – before the term casein.
24. In claim 41, line 4 insert the term – beta- – before the term casein.
25. In claim 41, line 7 insert the term – beta- – before the term casein.
26. In claim 42, line 1, delete the term “modified” and in line 2, delete the phrase, “or fragments thereof”.
27. In claim 42, line 3 insert the term – beta- – before the term caseins.
28. Replace claim 43 with the following:
 43. The product according to claim 42 wherein in the sequences Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2), the sequences are modified by the steps of:
 - a) removal of said sequences;

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- b) substitution of said sequences by the sequence Val-Glu-Pro-Ile-Pro (SEQ ID NO: 6); or
 - c) a combination of steps a) or b).
- 29. In claim 44, line 1 insert the term – beta- – before the term casein.
- 30. In claim 45, line 2 delete the phrase, “or fragments thereof”.
- 31. In claim 45, line 2, insert the term – beta- – before the term casein, and in line 4 insert the term – beta- – before the term caseins.
- 32. In claim 46, line 2 insert the term – beta- – before the term casein.
- 33. In claim 46, line 3 insert the term – beta- – before the term casein.
- 34. In claim 46, line 7 insert the term – beta- – before the term casein.
- 35. In claim 47, line 3 delete the term “immunogenic”.
- 36. In claim 47, line 4 insert the term – beta- – before the term caseins.
- 37. Replace claim 48 with the following:
 - 48. The method according to claim 47 wherein the sequences Pro-Gly-Pro-Ile-His (SEQ ID NO: 1) and Pro-Gly-Pro-Ile-Pro (SEQ ID NO: 2), the sequences are modified by the steps of:
 - a) removal of said sequences;
 - b) substitution of said sequences by the sequence Val-Glu-Pro-Ile-Pro (SEQ ID NO: 6); or
 - c) a combination of steps a) or b).
- 38. In claim 49, line 1 insert the term – beta- – before the term caseins.
- 39. In claim 50, line 2 insert the term – beta- – before the term casein.
- 40. In claim 50, line 2 delete the phrase, “or fragments thereof”.
- 41. In claim 50, line 4 insert the term – beta- – before the term caseins.
- 42. In claim 51, line 1 insert the term – beta- – after the term recombinant.
- 43. In claim 51, line 3 insert the term – beta- – before the term casein.
- 44. In claim 51, line 7 insert the term – beta- – before the term casein.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)-872-9306.

TNT

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